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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,391	12/17/2001	Michael J. Brubaker	P02375	2415

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EXAMINER
OH, SIMON J

ART UNIT	PAPER NUMBER
1615	6

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/023,391	Applicant(s) BRUBAKER ET AL.	
	Examiner Simon J. Oh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-39 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-39 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith *et al.* (U.S. Patent No. 5,378,475) in view of Yaacobi (U.S. Patent No. 6,413,540, B1), Langer *et al.* (U.S. Patent No. 4,657,543), Ashton *et al.* (U.S. Patent No. 5,773,019), and Guo *et al.* (U.S. Patent No. 6,375,972 B1).

The Smith *et al.* patent teaches an implantable sustained-release drug delivery device with an inner core or reservoir comprising an effective agent, an impermeable first coating layer, and a permeable second coating layer. The first coating covers at least a portion of the inner core and leaves a small portion of the core uncovered. The second coating layer completely covers the first coating layer and the uncovered portion of the core (See Abstract). In alternative embodiments of the disclosed invention, another permeable coating may be present between the core or reservoir and the impermeable coating; a suture tag and an impermeable cap may also be included, and the impermeable cap may be positioned such that there is a passage which allows passage of the drug (See Column 4, Lines 36-57; and Figures 1 and 2). Methods of administration include inserting, injecting, or implanting the device in a mammalian organism (See Column 4, Lines 58-68). Drugs suitable for use in the device include anti-cancer agents,

anti-viral agents, anti-glaucoma drugs, antibiotics, and immunological response modifiers (See Column 5, Line 36 to Column 6, Line 18). The material that may be used for the first and second polymer coating layers should be inert and insoluble; examples of suitable materials include polyvinyl alcohol and silicone rubbers (See Column 6, Lines 26-66). Cross-linked polyvinyl alcohol is particularly preferred for the second, permeable coating layer (See Column 8, Lines 49-68). An example is given where the device is implanted within the vitreous of test subjects for treatment (See Column 17, Example 4). Methods of device construction are also disclosed (See Columns 11, 13, and 18).

The Smith *et al.* patent does not teach a structure with a lip designed to retain a coated tablet in place, nor does it teach the use of a drug of low solubility.

The Yaacobi patent teaches a drug delivery device comprising an inner drug core and a body having an internal surface to be placed proximate to a target tissue (See Abstract). A retaining member prevents the drug core from falling out of the body. It may be in the form of a continuous rim or lip around the circumference of the opening in the body; alternatively, the retaining member may comprise multiple members that extend from the body into the opening (See Column 4, Lines 15-29). The body of the device is preferably made from an impermeable, biocompatible, non-bioerodable polymer; suitable materials for this device include silicone and polyvinyl alcohol (See Column 5, Lines 1-8 and 24-25). Pharmaceutical agents suitable for use in the device include antibiotics, anti-virals, steroidal and non-steroidal anti-inflammatory agents, combinations of anti-infective and anti-inflammatory agents, combinations of anti-glaucoma agents, neuroprotective drugs, and angiostatic steroids (See Column 5, Lines 31-65). In an alternate form of the disclosed invention, the inner core of the device may comprise a tablet

that further comprises a non-bioerodable hydrogel, which would still allow diffusion of the active agent (See Column 6, Lines 4-12). The Yaacobi patent also teaches methods of delivering a drug with the disclosed device (See Claim 3).

The Langer *et al.* patent is a teaching reference, which shows that polyvinyl alcohol is also a hydrogel (See Column 2, Lines 59-60).

The Ashton *et al.* patent teaches an implantable, sustained-release drug delivery device with an inner core containing an agent of low solubility, and a permeable polymer layer coating the core (See Abstract; and Column 5, Lines 13-17). Drugs suitable for use in the device include immune response modifiers, corticosteroids, angiostatic steroids, anti-parasitic agents, anti-glaucoma agents, antibiotics, differentiation modifiers, anti-viral agents, anti-cancer agents, non-steroidal anti-inflammatory agents, and combinations thereof. The disclosure emphasizes that the drugs to be used in the device should be of low solubility, and that standard techniques known in the art to obtain low-solubility forms of a drug can be used (See Column 5, Lines 34-52). The material that may be used for the polymer layer should be biologically compatible and non-bioerodable; examples of suitable materials include polyvinyl alcohol and silicone (See Column 5, Line 53 to Column 6, Line 8). The device may be fashioned with a suture tab; in an alternate form of the invention, the suture tab may be defined in part by a support ring structure (See Figures 2 and 4; and Column 7, Example 3). An example is given where the device is surgically implanted onto the sclera of test subjects (See Column 7, Example 2). Methods of treatment are also disclosed (See Claim 12).

The Guo *et al.* patent teaches a sustained-release drug delivery device comprising an inner core or reservoir including the effective agent (See Abstract). The teachings of the patent

address the problems of similar devices in the prior art, including device size, structural strength, and manufacturing uniformity (See Columns 3-4). The delivery system of the invention may be inserted directly into the vitreous, under the retina, or onto the sclera; the insertion itself may be achieved by injection of surgical implantation (See Column 5, Lines 5-9). Drugs suitable for use in the device include anti-cancer agents, anti-inflammatory agents, anti-glaucoma drugs, immunological response modifiers, neuroprotectants, and anti-virals (See Column 11, Line 62 to Column 12, Line 47). More than one agent may be included in the inner core or reservoir (See Column 15, Lines 61-64). Materials suitable for manufacturing the device include polyvinyl alcohol, cross-linked polyvinyl alcohol, silicone rubbers, gold, platinum, and surgical stainless steel (See Column 13, Lines 1-26). The patent also discloses that materials, such as polyvinyl alcohol, that are used in the device must be able to withstand certain processing steps such as heat curing without suffering deformation (See Column 13, Line 52 to Column 14, Line 3). In one embodiment, the device may comprise an impermeable body and a permeable plug (See Column 5, Lines 45-55). Methods of manufacturing the disclosed device may include techniques that are in accordance with conventional coating techniques (See Column 15, Lines 38-47).

It would be obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Smith *et al.*, Yaacobi, Ashton *et al.*, and Guo *et al.* into the objects of the instant application. As stated in *In re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA- 1980), "It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose." As this court explained in Crockett, 126 USPQ 186, 188 (CCPA- 1960),

the idea of combining them flows logically from their having been individually taught in the prior art. Similarly, the similar subject matter of Smith *et al.*, Yaacobi, Ashton *et al.*, and Guo *et al.* would lead one of ordinary skill in the art to create a device which encompasses the teachings of the patents, drawn to the subject matter of the instant application. The teachings of Yaacobi and Langer *et al.* would make obvious to one of ordinary skill in the art that the inner core of the device may comprise a tablet coated with polyvinyl alcohol for the purpose of modifying the release of the drug. In view of the teachings of Guo *et al.*, such a tablet can be cured without suffering deformation. It is the position of the examiner that the disclosure in Guo *et al.*, which states that methods of manufacturing the disclosed device may include techniques that are in accordance with conventional coating techniques, make obvious the claim limitation drawn to the formation of the permeable plug onto the unitary cup. Regarding other claim limitations not explicitly addressed by the prior art, it is the position of the examiner that the applicant has not clearly established by an objective showing of some additional unusual or unexpected result that the instantly claimed device provides any greater level of prior art expectation as claimed. Thus, the claimed invention as a whole is *prima facie* obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-34 of copending Application No. 10/378,374. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is a substantial structural similarity in the claimed devices, methods of administration, and methods of manufacture between the two applications. Sustained release features, the use of a drug core, the presence of a plug, similar or identical materials used in manufacture, similar or identical categories of active substances used, insertion or implantation of the claimed dosage form onto or near or around the eye are all features that are claimed in both applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

sjo
April 9, 2003

THURMAN K. PAGE
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